

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE PRESCRIPTION
OPIATE LITIGATION**

This document relates to:
Case No. 1:18-op-45817-DAP
COBB COUNTY, GA,

Plaintiff,

vs.

PURDUE PHARMA, et al.,

Defendants.

**KROGER DEFENDANTS' ANSWER TO PLAINTIFF'S
SUPPLEMENTAL AND AMENDED ALLEGATIONS TO BE ADDED TO
"SHORT FORM FOR SUPPLEMENTING COMPLAINT AND AMENDING
DEFENDANTS AND JURY DEMAND"**

Defendants, The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II (collectively "Kroger"), pursuant to the Stipulated Order Regarding Answering the May 19, 2021 Amended Complaints in the Five New Pharmacy Bellwether Cases (MDL ECF No. 3853, the "Stipulated Order"), answer Plaintiff's "Supplemental and Amended Allegations to be Added to 'Short Form for Supplementing Complaint and Amending Defendants and Jury Demand'" (ECF No. 17, the "Amended Complaint") as follows:

Statements Pursuant to Stipulated Order

A. Pursuant to the Stipulated Order (¶ 4), Kroger has no obligation to answer any prior complaints and pleadings incorporated by reference into the Amended Complaint. By not answering such prior complaints and pleadings, Kroger does not admit any of the allegations

in those prior complaints or pleadings and reserves all defenses to the claims and allegations of the prior complaints or pleadings. The fact that Kroger has not answered any prior complaints and pleadings in responding to the allegations of the Amended Complaint, based on the Stipulated Order, shall not and cannot be construed as an admission of any allegation in those prior complaints or pleadings and shall not be a basis for a default judgment with respect to any claims asserted in those prior complaints or pleadings. On this basis, Kroger does not answer paragraphs 3, 729-730 and 733 of the Amended Complaint. For clarity, Kroger denies any incorporated averments to the extent they are directed at Kroger and denies them specifically to the extent they claim Kroger acted improperly or failed to comply with the law. To the contrary, Kroger, at all times, acted properly and in accordance with its legal obligations. Kroger denies any and all liability to the Plaintiff in this matter.

B. Kroger answers only for itself. Pursuant to the Stipulated Order (¶ 5), Kroger has no obligation to answer any allegation or paragraph directed solely to other defendants and may so state in its Answer. On this basis, Kroger does not answer paragraphs 33-75, 79-83, 187-439, 460-502, 505-509, 512-528, 533, 537-538, 542, 549-551, 560-564, 570-597, 599, 606-616, 623-669 of the Amended Complaint. For clarity, Kroger denies any averments directed at Kroger, including in these paragraphs.

C. Pursuant to the Stipulated Order (¶¶ 6, 9), Kroger may identify the paragraphs that it denies in their entirety by paragraph number. Additionally, the Amended Complaint contains purported references to several documents and third-party publications and statements that have often been excerpted, paraphrased, characterized, and otherwise taken out of context. These third-party publications and statements should be considered, if at all, in context and in unmodified form, and Kroger hereby respectfully refers the Court to the respective third-

party publications and statements for their complete contents. On this basis, Kroger denies paragraphs 1-2, 4-32, 84-99, 101-147, 149-186, 503-504, 510-511, 529-532, 534-536, 539-541, 544-548, 552-559, 565-569, 600-605, 618-622, 671-728, 731-732, 734-753 of the Amended Complaint: as factually incorrect; as calling for legal conclusions; as purporting to state facts as to which Kroger lacks sufficient knowledge to respond; as based on the Plaintiff's vague, ambiguous, and improper characterizations; and/or to the extent Plaintiff's purport to quote from sources other than the Amended Complaint, including undisclosed or unidentified sources. Kroger specifically denies any and all allegations that it distributed or dispensed opioid medications in violation of the Controlled Substances Act, its associated regulations, or any other state or federal law or regulation. Kroger also specifically denies that its distribution of opioid medications to Kroger pharmacies or dispensing of those medications from those Kroger pharmacies caused or contributed to any public nuisance, and denies allegations directed against Kroger in those paragraphs.

Preliminary Statement

A. Kroger does not contest that there are certain harms associated with improper opioid use, including opioid addiction; however, Kroger's overriding contention in this Answer is simply that it is not responsible or liable for the allegations made in the Complaint or the choices certain individuals may have made to use opioid medications improperly and any resulting harms to those individuals or third parties.

B. All subparts, footnotes, headings, or graphical addenda in Paragraphs in the Complaint are treated as part of the Paragraph that is being responded to and are not separately dealt with. To the extent these materials need to be specifically addressed, Kroger denies them.

C. Kroger denies each allegation contained in the Complaint, except as specifically admitted, and any factual averment admitted herein is admitted only as to the specific

facts and not as to any conclusions, characterizations, implications, innuendos, or speculation contained in any averment or in the Complaint, as a whole.

D. The Complaint contains and references documents, websites, books, guides, pamphlets, articles, third-party publications, and statements that are excerpted, paraphrased and characterized. Such items constitute the best evidence and speak for themselves, and references to them should be considered, if at all, in context and in unmodified form. Kroger objects to the references to such items to the extent the proper foundation has not been established and require review of information outside the pertinent pleadings, and Kroger denies any characterizations thereof. To the extent such items are considered, Kroger respectfully refers the Court to the respective materials for their complete contents.

E. The Complaint, on occasions, uses vague and ambiguous language, like “substantial,” “multiple sources,” and an undefined “etc.” On such occasions, Kroger has no recourse but to deny those allegations, based on imprecise terminology.

F. Kroger admits that certain provisions of state and federal law impose a duty on it to report suspicious orders and other responsibilities, and states that Kroger fulfilled that duty and those responsibilities, and denies any allegations directed at Kroger, based on duties and obligations imputed by Plaintiff on Kroger.

G. With respect to paragraphs in the Complaint alleging the DEA’s reminders of obligations, Distributors’ Initiatives, conferences, guidance, letters, instructions, meetings, and presentations, Kroger asserts that such DEA actions speak for themselves, and Kroger denies any characterizations thereof, denies any allegations directed at Kroger, but Kroger is without knowledge or information sufficient to form a belief as to the truth of the allegations in those Paragraphs of the Complaint and, on that basis, denies those allegations.

H. Kroger reserves the right to seek to amend and supplement its Answer as may be appropriate or necessary.

Answers to Remaining Allegations

The paragraphs below Answer the correspondingly enumerated paragraphs of the Complaint.

76. Kroger admits that The Kroger Co. is an Ohio corporation, with its principal place of business in Cincinnati, Ohio; that Kroger Limited Partnership I is an Ohio limited partnership, with its principal place of business in Cincinnati, Ohio; and that Kroger Limited Partnership II is an Ohio limited partnership. Kroger denies that Kroger Limited Partnership II's principal place of business is in Columbus, Ohio. The last sentence in Paragraph 76 of the Complaint is a nomenclature utilized by the Plaintiff to which no response is required, but Kroger denies all allegations directed at Kroger.

77. Kroger admits that it operates approximately 2,200 pharmacies in certain areas of the United States and denies the remaining allegations in Paragraph 77 of the Complaint.

78. Kroger objects to Paragraph 78 of the Complaint, as it is impermissibly vague and ambiguous ("at all relevant times" and "certain"). Answering further, Kroger admits that it filled legitimate prescriptions, including prescriptions for opioid medication in Georgia and Cobb County, that it distributed Hydrocodone only to its own pharmacies prior to October 6, 2014, when it was classified as a Schedule III opioid, including in Georgia and Cobb County, and denies the remaining allegations in Paragraph 78.

100. Kroger admits only that it operates over 2,200 pharmacies in certain areas of the United States, including Georgia, that it distributes certain prescription opioids to its pharmacies, denies the remaining allegations directed at Kroger, and is without knowledge or

information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 100 of the Complaint and, on that basis, denies those allegations.

148. Kroger admits that Colleen Lindholz, President, Kroger Health, currently chairs the NACDS board, admits that NACDS is a trade association that, *inter alia*, represents pharmacies, that the NACDS Board promulgates strategy for the association, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 148 of the Complaint and, on that basis, denies those allegations.

440. Kroger admits only that it had certain pertinent information relating to filling of prescription procedures at its pharmacies, that it followed federal and state laws relating to its dispensing and internal distribution actions, and denies the remaining allegations in Paragraph 440 of the Complaint.

441. Kroger denies the allegation in Paragraph 441 of the Complaint.

442. Kroger denies the allegations in Paragraph 442 of the Complaint.

443. Kroger denies the allegation in Paragraph 443 of the Complaint.

444. Kroger objects to the undefined timeframe, quotations, and terms such as “appears” and “aiming” as impermissibly vague and ambiguous, and hence denies those allegations. Answering further, Kroger’s process for reviewing orders has evolved over time. Kroger admits that its Pharmacy Managers review certain opioid orders, admits that Kroger has computer and other systems in place that track inventory, admits that its Pharmacy Coordinators could launch inquiries and conduct internal investigations about a single pharmacy’s opioid medication orders and activity, and denies the remaining allegations in paragraph 444 of the Complaint.

445. Kroger objects to the undefined quotations in Paragraph 445 of the Complaint, as impermissibly vague and ambiguous, and hence denies those allegation, and further states that any documents referenced in Paragraph 445 collectively and in their entirety speak for themselves, and Kroger denies any characterization thereof.

446. Kroger objects to Paragraph 446 of the Complaint as it is impermissibly vague and ambiguous, and does not define the document or who utilized it, and, on that basis, denies those allegations. Answering further, Kroger asserts that its SOM training materials in their entirety speak for themselves, and Kroger denies any mischaracterization thereof.

447. Kroger denies the allegation in Paragraph 447 of the Complaint.

448. Kroger denies the allegation in Paragraph 448 of the Complaint.

449. Kroger denies the allegation in Paragraph 449 of the Complaint.

450. Kroger denies the allegation in Paragraph 450 of the Complaint.

451. Kroger denies the allegation in Paragraph 451 of the Complaint.

452. The DEA's investigation of any Kroger entity speaks for itself, and Kroger denies any characterization thereof, and denies the remaining allegations in Paragraph 452 of the Complaint.

453. The DEA's settlement with any Kroger entity speaks for itself, and Kroger denies any characterization thereof; Kroger also asserts that any settlements are confidential, and denies the remaining allegations in Paragraph 453 of the Complaint.

454. The DEA's press release concerning settlement with any Kroger entity speaks for itself, and Kroger denies any characterization thereof, and asserts that it followed federal and state laws relating to its dispensing and internal distribution actions, and denies the remaining allegations in Paragraph 454 of the Complaint.

455. Kroger denies the allegation in Paragraph 455 of the Complaint.

456. Kroger denies the allegation in Paragraph 456 of the Complaint.

457. Kroger objects to the undefined timeframe as impermissibly vague and ambiguous, and hence denies those allegations. Answering further, Kroger asserts that these processes have evolved over time, Kroger admits that its pharmacies obtain opioids and other prescription medicines from self-distribution, and from Cardinal Health, and receives communications from Cardinal Health, and denies the remaining allegations in Paragraph 457 of the Complaint.

458. Kroger admits that it utilizes a program called NARxCHECK where available, the program has certain specifications, informational aspects, and benefits, that speak for themselves, and Kroger denies any characterization thereof, and denies the remaining allegations in Paragraph 458 of the Complaint.

459. Kroger denies the allegation in Paragraph 459 of the Complaint.

543. Kroger denies the allegation in Paragraph 543 of the Complaint.

598. Kroger denies the allegations in Paragraph 598 of the Complaint directed at Kroger and is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 598 of the Complaint and, on that basis, denies those allegations.

617. Paragraph 617 of the Complaint refers to a Cardinal document that speaks for itself, and Kroger denies any characterization thereof, but Kroger is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 617 of the Complaint and, on that basis, denies those allegations.

670. Paragraph 670 of the Complaint references two DEA settlements that speak for themselves, and Kroger denies any characterizations thereof, and Kroger asserts that the settlements are confidential. Answering further, Kroger asserts that the settlement referenced in Paragraph 670 involved dispensing activities that occurred outside of Georgia, and denies the remaining allegations.

JOINDER IN JURY DEMAND

754. Kroger joins in Plaintiff's demand that the above-captioned action be tried to a jury. Inasmuch as Plaintiff's Complaint indicates that a jury trial has already been requested, a jury fee is not tendered herewith. However, in the event that a jury trial is not provided based on the request of Plaintiff, Defendants will tender the appropriate fee.

KROGER'S AFFIRMATIVE DEFENSES

Having answered the allegations of Plaintiff's Complaint, and having denied any liability whatsoever, Kroger further denies any allegations that have not been expressly admitted and sets forth below its defenses. By setting forth these defenses, Kroger does not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiff. Moreover, Kroger does not intend these defenses to be, nor shall they be construed as, an acknowledgement that any particular issue or subject matter is relevant to Plaintiff's allegations. Kroger does not admit or acknowledge that it bears the burden of proof or burden of persuasion with respect to any such defense. Upon completion of discovery, if the facts warrant, Kroger may withdraw any of these defenses as may be appropriate. Kroger reserves the right to (i) rely on any other applicable defenses set forth in any Answer or listing of affirmative defenses of any other defendant in this Action, (ii) rely on any other defenses that may become

apparent during fact or expert discovery in this matter, and (iii) to amend its Answer to assert any such defenses.

First Affirmative Defense

The Complaint fails to state a claim against these Defendants upon which relief can be granted.

Second Affirmative Defense

This Court lacks subject matter jurisdiction over all or some of the claims asserted by the Plaintiff.

Third Affirmative Defense

To the extent applicable, the Court lacks subject matter jurisdiction to address any violations of the Georgia Pharmacy Practice Act, either (1) for failure to comply with any administrative remedies under the Act, (2) because the Georgia Pharmacy Practice Act does not give rise to a private cause of action, and/or (3) because the Court has already dismissed any claims or cause of action arising from or related to the Georgia Pharmacy Practice Act.

Fourth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrine.

Fifth Affirmative Defense

The Plaintiff lacks standing to assert all or some of its claims in this lawsuit.

Sixth Affirmative Defense

Plaintiff's claims are barred by the voluntary payment doctrine.

Seventh Affirmative Defense

Plaintiff's claims are barred by the doctrine of unclean hands.

Eighth Affirmative Defense

Plaintiff's claims are barred by the doctrine of *in pari delicto*.

Ninth Affirmative Defense

Plaintiff's claims are not ripe and/or have been mooted.

Tenth Affirmative Defense

Plaintiff's claims and damages are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a municipality.

Eleventh Affirmative Defense

Plaintiff's claims are barred because Plaintiff are not the real parties in interest.

Twelfth Affirmative Defense

Plaintiff's claims are subject to all defenses that could be asserted if Plaintiff's claims were properly made by individuals on whose behalf Plaintiff seek to recover.

Thirteenth Affirmative Defense

Any injuries and/or damages sustained by Plaintiff may have been caused or contributed to by the negligence or actual conduct of Plaintiff and/or other persons, firms, corporations, or entities over whom Kroger had no control or right of control and for whom it is not responsible.

Fourteenth Affirmative Defense

A specific percentage of the tortious conduct that proximately caused the injury or loss to person or property is attributable to (i) Plaintiff, (ii) other parties from whom Plaintiff seeks recovery, and (iii) persons from whom Plaintiff does not seek recovery in this action, including, but not limited to, prescribing practitioners, non-party pharmacies and pharmacists, individuals and entities involved in diversion and distribution of prescription opioids, individuals and entities

involved in import, distribution, and sale of illegal opioids, individuals involved in procuring diverted prescription opioids and/or illegal drugs, delivery services, federal, state, and local government entities, and health insurers and pharmacy benefit managers, pursuant to the doctrine of comparative fault.

Fifteenth Affirmative Defense

Any recovery by Plaintiff must be reduced to account for the acts or omissions attributable to Plaintiff.

Sixteenth Affirmative Defense

Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already indemnified or, with reasonable certainty, will indemnify Plaintiff, in whole or in part, for any past or future claimed economic loss from any collateral source or any other applicable law.

Seventeenth Affirmative Defense

Any damages that Plaintiff may recover against Kroger must be reduced to the extent that Plaintiff is seeking damages for alleged injuries or expenses related to the same user(s) of the subject drugs, or damages recovered or recoverable by other actual or potential Plaintiff. Any damages that Plaintiff may recover against Kroger must be reduced to the extent they unjustly enrich Plaintiff.

Eighteenth Affirmative Defense

Plaintiff has failed to comply with the requirement that it identify each patient in whose claim(s) it has a subrogation interest and on whose behalf it has incurred costs.

Nineteenth Affirmative Defense

Plaintiff fails to plead that it reimbursed any prescriptions for any opioid sold by Kroger that harmed patients and should not have been written, or that Kroger's allegedly improper

conduct caused any health care provider to write any ineffective or harmful opioid prescriptions, or that any specific prescription was unauthorized, medically unnecessary, ineffective, or harmful.

Twentieth Affirmative Defense

Plaintiff's claims against Kroger do not arise from the same transactions or occurrences as its claims against other defendants, as required for joinder of parties.

Twenty-First Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the doctrines of superseding and intervening acts and/or causation.

Twenty-Second Affirmative Defense

To the extent Plaintiff has made a civil conspiracy claim against these Answering Defendants, and such claim has not been dismissed by the Court, there is no basis for joint and several liability among the Defendants, and Plaintiff's civil conspiracy should be dismissed, as it is an improper attempt to obtain such a result.

Twenty-Third Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Kroger has no legal duty to protect Plaintiff from the intentional criminal acts of third persons. Such criminal acts are superseding causes that extinguish any liability.

Twenty-Fourth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because its alleged injuries or damages were due to illicit use or abuse of medications.

Twenty-Fifth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because the derivative injury rule and the remoteness doctrine bars Plaintiff from recovering payments it allegedly made on behalf

of its residents to reimburse any expenses for health care, pharmaceutical care, and other public services.

Twenty-Sixth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, to the extent that it violated the Dormant Commerce Clause of the United States Constitution.

Twenty-Seventh Affirmative Defense

The Complaint fails to state a claim against Kroger because Plaintiff cannot establish a right common to the general public with which Kroger unreasonably interfered.

Twenty-Eighth Affirmative Defense

Kroger did not owe or breach any statutory or common law duty to Plaintiff.

Twenty-Ninth Affirmative Defense

Kroger appropriately, completely, and fully performed and discharged any and all obligations and legal duties arising out of the matters alleged in the Complaint.

Thirtieth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Kroger complied at all relevant times with all applicable laws, including all legal and regulatory duties.

Thirty-First Affirmative Defense

Plaintiff's claims are barred to the extent they are based on alleged violations of industry customs because purported industry customs do not create legal duties on Kroger.

Thirty-Second Affirmative Defense

To the extent applicable, Kroger is not a Wholesale Distributor as alleged in the Complaint and, hence, the Complaint is premised on a mistaken allegation against Kroger and should be dismissed against Kroger for that reason.

Thirty-Third Affirmative Defense

Kroger raises the Learned Intermediary Defense to the extent applicable, based on the allegations against Kroger, because Kroger fills valid prescriptions written by a physician acting in the capacity of a learned intermediary.

Thirty-Fourth Affirmative Defense

Any and all of the injuries or damages suffered by Plaintiff resulted solely from conduct and/or conditions for which Kroger is not responsible and for which it cannot be held liable.

Thirty-Fifth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because the harm alleged was proximately caused by the negligence, gross negligence, or intentional and malicious acts of intervening third parties not under Kroger's control, including, without limitation, pre-existing medical conditions.

Thirty-Sixth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because its alleged injuries or damages were caused by the misuse of the medications involved, by failure to use the medications properly, and/or by the alteration, modification, or criminal misuse of medications prescribed by third parties over whom Kroger had no control.

Thirty-Seventh Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because neither the users of the subject prescription medications nor their prescribers relied to their detriment upon any statement by Kroger in determining to use or prescribe the subject prescription medications.

Thirty-Eighth Affirmative Defense

Plaintiff's claims against Kroger are improperly joined with Plaintiff's claims against other Defendants and must be severed.

Thirty-Ninth Affirmative Defense

Plaintiff's claims against Kroger are barred because Kroger has complied with all applicable laws or regulations of the federal government and the State of Georgia.

Fortieth Affirmative Defense

Plaintiff's claims against Kroger are barred, in whole or in part, by the doctrines of laches, estoppel, and waiver.

Forty-First Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by Plaintiff's comparative or contributory fault including without limitation, on information and belief, its failure to:

- a. Develop and implement adequate policies and procedures to license and monitor physicians and other professionals prescribing the controlled substances at issue in the Complaint, and to discipline or terminate the licenses of those issuing prescriptions for other than legitimate purposes;
- b. Develop and implement adequate policies and procedures to license, monitor and inspect pain management clinics prescribing the controlled substances at issue in the Complaint, and to discipline or terminate the licenses of those issuing prescriptions for other than legitimate purposes;
- c. Develop and implement adequate policies and procedures to license, monitor and inspect pharmacies, pharmacists and other dispensers to ensure that they filled only legitimate prescriptions for controlled substances at issue in the Complaint, and to discipline or

terminate the licenses of those dispensing such prescription drugs for other than legitimate purposes;

d. Develop and mandate use of an effective controlled substance monitoring database to identify rogue pharmacies, other dispensers and doctors, and drug abusers and take appropriate action against them;

e. Develop, implement and adequately fund prescription drug abuse prevention and treatment programs;

f. Develop, implement and adequately fund programs to address homelessness within the State of Georgia;

g. Adequately fund mental and behavioral health services throughout the State of Georgia;

h. Adequately police the illicit diversion and consumption of prescription medications, and to enforce the Georgia Controlled Substances Act, the Georgia Pharmacy Practice Act and regulations promulgated thereunder.

Forty-Second Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff failed to join one or more indispensable parties.

Forty-Third Affirmative Defense

To the extent applicable, Plaintiff's claims against Kroger are barred, in whole or in part, by the applicable statutes of limitations and repose.

Forty-Fourth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because they violate the *Ex Post Facto* clauses of Article I of the United States Constitution and Article II, Sec. I of the Georgia

Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Forty-Fifth Affirmative Defense

Recovery from Kroger is barred, in whole or in part, by the free public services doctrine.

Forty-Sixth Affirmative Defense

Plaintiff's claims against Kroger are barred, in whole or in part, by the economic loss and/or municipal cost recovery doctrine.

Forty- Seventh Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution as well as Article I, Sec. I of the Georgia Constitution, because substantive due process forbids the retroactive imposition and unclear legal interpretations of the Georgia Uniform Controlled Substances Act and its federal counterpart, including, without limitation, the federal Controlled Substances Act and the Food, Drug, and Cosmetic Act ("FDCA").

Forty-Eighth Affirmative Defense

Kroger's rights under the Due Process Clause of the U.S. Constitution and Georgia State Constitution or statutes are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding, including by Plaintiff's use of a contingency fee contract with private counsel.

Forty-Ninth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because federal agencies have exclusive or primary jurisdiction over the matters asserted in the Complaint.

Fiftieth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by conflict preemption as set forth in the United States Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

Fifty-First Affirmative Defense

Plaintiff's claims are preempted insofar as they conflict with Congress's purposes and objectives in enacting relevant federal legislation and authorizing regulations, including the Hatch-Waxman Amendments to the FDCA and implementing regulations. *See Geier v. Am. Honda Co.*, 529 U.S. 861 (2000).

Fifty-Second Affirmative Defense

To the extent Plaintiff asserts claims that depend solely on violations of federal law, including any claims with respect to Kroger's compliance with statutes or regulations administered and/or enforced by the DEA, such claims are barred and should be dismissed. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

Fifty-Third Affirmative Defense

Plaintiff's claims are barred to the extent they are based on any allegations involving failure to provide adequate warnings or information, because all warnings or information that accompanied the allegedly distributed products were approved by the United States Food & Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*), as amended, or Section 351, Public Health Service Act (42 U.S.C. § 262), as amended, or the warnings and information provided were those stated in monographs developed by the United States Food & Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

Fifty-Fourth Affirmative Defense

To the extent that Plaintiff relies on letters or other informal guidance from the DEA to establish Kroger's regulatory duties, such informal guidance cannot enlarge Kroger's regulatory duties in the absence of compliance by DEA with the requirements by the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*

Fifty-Fifth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the Restatement (Second) of Torts § 402A, Comments j and k, and Restatement (Third) of Torts: Products Liability § 6.

Fifty-Sixth Affirmative Defense

Kroger is not liable for any statements in the Manufacturer Defendants' branded or unbranded materials.

Fifty-Seventh Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because the State of Georgia specifically licensed Kroger to distribute the controlled substances referred to in the Complaint to purchasers with valid prescriptions within the relevant Counties in Georgia.

Fifty-Eighth Affirmative Defense

Plaintiff's commencement and prosecution of this action is arbitrary and capricious, and its claims are contrary to the Georgia Controlled Substances Act, Georgia Code Ann. § 16-13-20, *et seq.*, and rules and regulations promulgated pursuant to that Act and its federal counterpart.

Fifty-Ninth Affirmative Defense

Plaintiff's claims against Kroger are barred, in whole or in part, because it has suffered no damages because of the matters alleged in the Complaint.

Sixtieth Affirmative Defense

The Plaintiff is not entitled to the asserted damages, as it seeks as damages the costs it allegedly incurred in providing public services, to the extent there is no express statutory provision establishing such a remedy.

Sixty-First Affirmative Defense

Any injuries and/or damages sustained by Plaintiff were caused, in whole or in part, by its own failure to effectively enforce the law and prosecute violations thereof and any recovery by Plaintiff is barred or, alternatively, should be diminished according to its own fault.

Sixty-Second Affirmative Defense

Any recovery by Plaintiff may be barred or limited by the principles of informed consent and assumption of the risk, whether primary, express, or implied.

Sixty-Third Affirmative Defense

Kroger asserts its right to a proportionate reduction, based on the negligence or other conduct of any settling tortfeasor, responsible third party, or Plaintiff, of any damages found against Kroger.

Sixty-Fourth Affirmative Defense

To the extent that Plaintiff seeks equitable relief against Kroger, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

Sixty-Fifth Affirmative Defense

Plaintiff's claims for unjust enrichment are barred because Kroger has not accepted or retained any benefits under circumstances where it would be inequitable for Kroger to do so.

Sixty-Sixth Affirmative Defense

Plaintiff's claims for unjust enrichment are barred because Plaintiff has no authority to bring such claims on behalf of itself or the citizens of Georgia.

Sixty-Seventh Affirmative Defense

Plaintiff's claims for unjust enrichment are barred because Plaintiff did not pay Kroger any of the amounts sought.

Sixty-Eighth Affirmative Defense

Plaintiff's public nuisance claim are barred to the extent that it lacks the statutory authority to bring a public nuisance claim under Georgia law or their own applicable county or municipal codes or regulations.

Sixty-Ninth Affirmative Defense

Plaintiff's claim of public nuisance is barred or limited because no action of Kroger involved interference with real property; illegal conduct perpetrated by third parties involving the use of an otherwise legal product does not involve a public right against Kroger sufficient to state a claim for public nuisance; the alleged public nuisance would have impermissible extraterritorial reach; and the alleged conduct of Kroger is too remote from the alleged injury as a matter of law and due process.

Seventieth Affirmative Defense

To the extent that Plaintiff is alleging fraud, fraudulent concealment, or similar conduct for causes of action not already dismissed by the Court, Plaintiff has failed to plead fraud with sufficient particularity as required Georgia Code Ann. § 9-11-9(b).

Seventy-First Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Kroger did not engage in misleading, unfair, actionable misrepresentation, or deceptive conduct.

Seventy-Second Affirmative Defense

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest because of the conduct of Kroger as alleged in the Complaint.

Seventy-Third Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to mitigate damages. Ga. Code Ann. § 51-11-7.

Seventy-Fourth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because the claims are speculative, uncertain, hypothetical, and remote; and because of the impossibility of ascertaining and allocating the alleged damages.

Seventy-Fifth Affirmative Defense

Plaintiff's claims are barred to the extent they relate to Kroger's alleged advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitution of the State of Georgia.

Seventy-Sixth Affirmative Defense

Plaintiff's claims are barred to the extent they rely, explicitly or implicitly, on a theory of market-share liability.

Seventy-Seventh Affirmative Defense

Plaintiff's claims for injunctive relief are barred because they are punitive in nature.

Seventy-Eighth Affirmative Defense

Plaintiff's claims are barred, reduced, and/or limited pursuant to the applicable Georgia statutory and common law regarding setoffs. Ga. Code Ann. §§ 51-12-33, 51-11-7.

Seventy-Ninth Affirmative Defense

Plaintiff's claims are barred, reduced, and/or limited to the extent that Kroger is entitled to a credit or setoff for all sums Plaintiff has received in the way of any and all settlements.

Eightieth Affirmative Defense

Plaintiff's Complaint is barred, in whole or in part, by the doctrines of acquiescence, settlement, or release.

Eighty-First Affirmative Defense

Kroger' s liability, if any, will not result from their conduct but is solely the result of an obligation imposed by law and, thus, Kroger is entitled to complete indemnity, express or implied, by other parties.

Eighty-Second Affirmative Defense

Plaintiff cannot obtain relief on its claims, based on actions undertaken by Kroger, of which Kroger provided notice of all material facts.

Eighty-Third Affirmative Defense

Kroger asserts all applicable defenses under Federal Rules of Civil Procedure 8(c) and 12(b) and/or Georgia Code Ann. §§ 9-11-8(c) and 9-11-12(b), as investigation and discovery proceed.

Eighty-Fourth Affirmative Defense

Plaintiff's claims for punitive or exemplary damages or other civil penalties are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and Article I, Section 120; Article I, Section I of the Georgia Constitution. Any law, statute or other authority purporting to permit the recovery of punitive damages or civil penalties in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages or civil penalties

and/or the amount, if any; (2) is void for vagueness in that it fails to provide adequate advance notice as to what conduct will result in punitive damages or civil penalties; (3) unconstitutionally may permit recovery of punitive damages or civil penalties based on harms to third parties, out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) unconstitutionally may permit recovery of punitive damages or civil penalties in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any award of punitive damages or civil penalties; (7) lacks constitutionally sufficient standards for appellate review of any award of punitive damages or civil penalties; (8) would unconstitutionally impose a penalty, criminal in nature, without according to Defendants the same procedural protections that are accorded to criminal defendants under the constitutions of the United States, this State, and any other state whose laws may apply; and (9) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996); *State Farm Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

Pursuant to Georgia Code Ann. § 51-12-5.1(b), the Plaintiff's claims for punitive damages must be established by clear and convincing evidence.

Plaintiff's claims for punitive damages are barred by the statute of limitations and requirements set forth in Georgia Code Ann. §§ 9-3-26, 9-3-33, and 51-12-5.1(b).

Eighty-Fifth Affirmative Defense

Plaintiff fails to assert claims and allege facts specific to Kroger sufficient to imply its participation in a civil conspiracy.

Eighty-Sixth Affirmative Defense

To the extent that Plaintiff seeks punitive, exemplary, or aggravated damages, any such damages are barred because the products at issue, and their labeling, were subject to and received pre-market approval by the FDA under 2 Stat. 1040, 21 U.S.C. §301.

Eighty-Seventh Affirmative Defense

The Georgia Uniform Deceptive Trade Practices Act cannot lie against Kroger as a matter of law and have not factual basis, entitling Kroger to its attorneys' fees and costs. Kroger also affirmatively seeks recovery for attorney's fees and costs arising from having to defend against claims or defenses made in bad faith. Georgia Code Ann. § 10-1-373.

Eighty-Eighth Affirmative Defense

Plaintiff has failed to state its damages with specificity as required under Georgia Code Ann. § 9-11-9(g).

Eighty-Ninth Affirmative Defense

Plaintiff's public nuisance claim is precluded by the Georgia legislature's comprehensive regulation of drugs of abuse. Ga. Code Ann. § 26-4-20(b).

Ninetieth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by collateral estoppel. Ga. Code Ann. § 26-4-1 *et seq.*

Ninety-First Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by res judicata. Ga. Code Ann. § 26-4-1 *et seq.*

Ninety-Second Affirmative Defense

Plaintiff's claims are barred, reduced, and/or limited pursuant to the applicable Georgia statutory and common law regarding liability caps. Ga. Code Ann. §§ 51-12-5.1, 51-13-1.

WHEREFORE, Kroger respectfully asks that this Court:

- A. Dismiss Plaintiff's Complaint, with prejudice, for the reasons set forth in Kroger' s Answer;
- B. Award Kroger its costs of litigation, including reasonable attorney and other fees incurred;
- C. Grant such other and further relief, including declaratory and equitable relief, as the Court deems appropriate.

DATED this 12th day of October 2021.

**THE KROGER CO., KROGER LIMITED
PARTNERSHIP I AND KROGER LIMITED
PARTNERSHIP II**

By Counsel

/s Ronda L. Harvey

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that true and correct copy of the foregoing **KROGER DEFENDANTS' ANSWER TO PLAINTIFF'S SUPPLEMENTAL AND AMENDED ALLEGATIONS TO BE ADDED TO "SHORT FORM FOR SUPPLEMENTING COMPLAINT AND AMENDING DEFENDANTS AND JURY DEMAND"** was served via the Court's CM/ECF system to all counsel of record via electronic filing on this 12th day of October 2021.

/s/ Ronda L. Harvey
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